UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 31, 2003

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 211-62 / Low pH Phenolic 256
DP Barcode: D287247

From: Ian Blackwell, Biologist
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Product Science Branch
Antimicrobials Division (7510C)

Through: Emily Mitchell, Team Leader Emily Mitchell 5/2/03
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To: Adam Heyward, PM 34 / Lisa McKelvin
Regulatory Management Branch I
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Applicant: Central Solutions, Inc.

Formulation From Label:

Active Ingredient(s)	% by wt
Ortho-Phenylphenol	8.085
Orthobenzyl-Benzyl-para-Chlorophenol	6.650
Inert Ingredient(s)	85.265
Total	100.00

I **BACKGROUND:** Central Solutions, Inc., has submitted one antimicrobial efficacy study to support new labeling claims for their product, "Low pH Phenolic 256". This data package contained EPA Form 8570-35 (Data Matrix), one study (MRID No. 458097-01), a Statement of No Data Confidentiality Claims for the study, the proposed label, and correspondence between the applicant's representative and EPA.

The product, Low pH Phenolic 256 (EPA Reg. No. 211-62), is an EPA-approved disinfectant (bactericide, tuberculocide, fungicide, virucide) for use on hard, non-porous surfaces in hospital and commercial environments, and in animal facilities. Against most pathogens, the label claims effectiveness in hard water up to 400 ppm in the presence of 5% blood serum. The applicant requested an amendment to the registration of this product to add claims for effectiveness against the Foot and Mouth Disease virus. Foot and Mouth Disease Virus is considered to be a disease of economic significance and requires the submission of antimicrobial efficacy data. The study was conducted at the Institute for Animal Health, Pirbright Laboratory, Ash Road, Pirbright, Surrey GU24 0NF, United Kingdom.

In a letter dated November 12, 2002, the applicant's representative stated that the product, Cenphene, is identical in formulation to the product, Low pH Phenolic 256, and that "Cenphene" is simply an alternate brand name for the registration.

II **Use Directions**

The product is designed to be used for disinfecting hard, non-porous surfaces such as door handles, medical bed surfaces, springs, wheelchairs, walls, floors, light switches, linen carts, stretcher wheels, hampers, telephones, clean up carts, bassinets, dressing carts, toilet bowl surfaces, urinal surfaces, showers, bathtubs, bed frames, mattress springs, impervious vinyl surfaces, counter tops, table tops, sinks, waste containers, lockers, desks, patient transfer lifts, patient scales, examination tables, dental chairs, medical lamps, stethoscopes, bedpans, blood donor chairs, crutches, instrument trays, and operating tables.

Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant against the Foot and Mouth Disease virus: Remove heavy soil or gross filth. Clean all surfaces with soap or detergent. Rinse surfaces with water. Prepare a use solution by adding ½ ounce of the product per gallon of water (a 1:256 dilution according to the label). Apply the use solution using a mop, cloth, sponge, or hand-pump trigger sprayer so as to thoroughly wet surfaces. Allow surfaces to remain wet for 10 minutes. Let air dry.

III Agency Standards for Proposed Claims

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products Test (for spray disinfectants) must be used in developing data for virucides intended for use upon dry inanimate, environmental surfaces (e.g., floors, tables, cleaned dried medical instruments). To simulate in-use conditions, the specific virus to be treated are be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. However, Foot and Mouth Disease virus is one of the few organisms that is not tested using a carrier assay. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

IV Comments on the Submitted Efficacy Studies

1 MRID 458097-01: "Test for Efficacy Against Foot and Mouth Disease Virus" for Cenphene, by Stuart Williams. Study conducted at Institute for Animal Health, Pirbright Laboratory, United Kingdom. Project No. – DIS P05/02. Study completion date – September 30, 2002.

This study was conducted against the Foot and Mouth Disease Virus (Strain OBFS 1860), using BHK 21 cell cultures as the host system. Two lots (Lot Nos. 04152014 and 01222009) of the product, Cenphene, were tested according to a method designed by the Institute of Animal Health and adopted by the United Kingdom's Department for Environment, Food and Rural Affairs for the UK registration of disinfectants. The stock virus titer contained a 1% organic soil load (fetal calf serum). The product was tested at 1:64, 1:128, and 1:256 dilutions. The product was initially diluted 1:6.4, 1:12.8, and 1:25.6 in distilled water. For each product dilution, 1 mL of the test organism and 1 mL of the use solution were added to 8 mL of sterile WHO hard water (342 ppm hardness; containing 1% fetal calf serum), to achieve an additional 1:10 dilution. The

mixture pH was measured and recorded immediately upon mixing. Each mixture was held at 4°C for 10 minutes. After exposure, serial ten-fold dilutions were prepared in Eagles (Glasgow) medium supplemented with L-glutamine, 10% fetal calf serum and antibiotics. The medium was removed from fifteen 6-well plates containing BHK21 cells, then the cells were washed with PBS. Two hundred µL (200 µL) of each dilution was inoculated into three separate wells of the plates. The plates were incubated at 37°C for 1 hour. Two mL (2 mL) Noble agar overlay medium was added to each well of the plates, then incubated for 48 hours at 37°C. Following incubation, 2 mL Methylene Blue Stain was added to each well and the plates were incubated at room temperature for 24 hours. After incubation, the agar was washed from the plates and the plates were examined visually for the presence or absence of plaques to confirm or rule out the presence or absence of the test organism. Controls included cytotoxicity and virus titer controls.

V Results

MRID Number	Organism	Results				
		Dilution	Cytotoxicity	Test Results	Viral Log Reduction	Viral Titer Control
		Lot No. 04152014				
458097-01	Foot and mouth disease virus (OBFS 1860)	1:64 1:128 1:128 1:256 1:256	not reported	NDP NDP NDP NDP NDP	>6.82 >6.82 >6.82 >6.82 >6.82	6.82 $\log_{10}$
		Lot No. 01222009				
		1:64 1:128 1:128 1:256 1:256	not reported	NDP NDP NDP NDP NDP	>8.40 >8.40 >8.40 >8.40 >8.40	8.40 $\log_{10}$

VI Conclusions

1 MRID No. 458097-01: The submitted efficacy data support the use of the product, Cenphene, as a disinfectant with virucidal activity when tested against the Foot and Mouth Disease Virus in the presence of 342 ppm hard water and a 1% organic soil load (fetal calf serum) on hard, non-porous surfaces for a contact time of 10 minutes at product dilutions of 1:64, 1:128, and 1:256. Complete inactivation (no detectable plaques in subcultures) of the virus was reported.

VII Recommendations

1 The proposed label claims (as supported by data in MRID No. 458097-01) are acceptable regarding the use of the product, Low pH Phenolic 256, as a disinfectant against the Foot and Mouth Disease Virus on hard, non-porous surfaces for a contact time of 10 minutes at product dilutions of 1:64, 1:128, and 1:256.

A Information about product efficacy against the Foot and Mouth Disease virus [page 8 of the proposed label] is misleading. The first text block on the page notes that the product is effective in the presence of 400 ppm hard water and 5% blood serum. The last text block on the page notes that the product is effective against the Foot and Mouth Disease virus; however, the label does not indicate that product effectiveness against the Foot and Mouth Disease is under the conditions of 342 ppm hard water and a 1% soil load. This portion of the label must be changed to state that effectiveness of Registration Number 211-62 against the Foot and Mouth Disease is under the conditions of 342 ppm hard water and a 1% soil load.

B Several portions of the submitted label name species of bacteria or fungi without italicizing them. Each of the species of bacterium and/or fungus listed on the product label must be printed in italics.